REGULATORY GUIDE B6

X-RAY FACILITY SHIELDING PLANS

South Carolina Department of Health
and Environmental Control

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Each facility possessing x-ray units requiring shielding plans must submit the appropriate information and comply with Title B. This guide is intended to help facilities in complying with Regulation 61-64, X-Rays (Title B).

SUBMISSION OF SHIELDING PLANS (See RHB 4.4)

Shielding plans are required to be reviewed and submitted by a registered Class III, Class IV, or Class VII vendor. A facility may not submit their own shielding plan unless they are also registered as a Class III, Class IV, or Class VII vendor. Shielding plans will not be accepted from unregistered vendors. A list of registered vendors is available from the Department. Before a plan can be reviewed, a fee of $62.50 must be paid. The $62.50 should be sent in the form of a check or money order made out to SCDHEC, and submitted with the shielding plan.

SHIELDING PLAN REQUIREMENTS (See RHB 4.4.1)

All new installations of x-ray equipment must have an approved shielding plan. In addition, any facility that is modifying an existing facility must also have an approved plan.

Shielding plans are required for:

1) All diagnostic medical x-ray units installed at new facilities.

2) Relocation of a unit within a facility.

3) All installations of therapeutic x-ray or accelerator units.

4) All installations of x-ray equipment at veterinary offices.

5) All industrial x-ray units used in shielded room configurations.

6) All dental cephalometric and TMJ units.

7) Replacement of an existing x-ray unit at a facility, to include the control, and/or generator.

8) Table bone density units (or area survey if **prior** approval is granted)

9) Mobile and portable radiographic units with a permanent cassette holder as addressed in RHB 4.4.11

Shielding plans **may be** required for:

1) Modifications to an existing approved installation, such as moving the operator's barrier, or installing vertical cassette holder.

2) Changes to an approved plan that may affect the shielding requirements, such as changing the film/screen system used, etc.

3) Dental intraoral units that are installed in modular type cabinets where there are not complete barriers between adjacent areas.

The only units that generally do not require shielding plans to be submitted are dental intraoral units installed in rooms with complete walls, and most industrial and analytical x-ray equipment, as well as peripheral bone density units. In those cases where a plan may or may not be required, please contact the Department for assistance. **DO NOT** assume that a new plan is not needed.

INFORMATION REQUIRED FOR SHIELDING PLAN REVIEW

Attached is a list of all information that is required to be submitted for shielding plan review. Shielding plans will not be accepted for review if this information is not included.

DEPARTMENTAL REVIEW OF SHIELDING PLANS (See RHB 4.4.1)

The Department will review shielding plans for adequacy according to the National Council of Radiation Protection and Measurements, Handbook 49, "Medical X-ray and Gamma-ray Protection for Energies up to 10 MeV," Handbook 35, "Dental X-ray Protection," Handbook 51 "Radiation Protection Design Guidelines for .1-100 MeV Particle Accelerator Facilities," or an equivalent reference.

After review and approval of a shielding plan, the Department may require additional modifications if an analysis indicates the possibility of an individual receiving a dose in excess of the applicable limits.

After a plan is reviewed and approved, the Department issues a shielding approval letter. This letter should be retained by both the vendor and the facility for future reference.

DESIGN REQUIREMENTS

Attached is the design criteria for new x-ray equipment installations. All installations in new facilities are required to meet these criteria. If the design criteria cannot be followed, such as replacement of equipment in an existing facility, the registrant may offer alternative design criteria to the Department for approval. The alternative design must afford the same degree of safety as the specified criteria. If a particular installation cannot reasonably meet the required design criteria, the shielding plan should be submitted to the Department along with a letter stating why the criteria cannot be met. The Department will give consideration for alternate designs provided that the intent of the regulations is being met.

In addition, the following conditions must be met:

1) All wall, floor, and ceiling areas exposed to the useful beam must have primary barriers. Primary barriers must extend to a minimum height of at least 2.13 meters or 7 feet above the floor.
2) Secondary barriers must be provided in all wall, floor, and ceiling areas not having primary barriers.
3) The operator's position at the control must be in a protected area.

Mobile and Portable X-ray systems used in conjunction with a permanently installed cassette holder shall be considered a stationary radiographic system and shall meet the requirements for such an installation as discussed in RHB 4.4.11. Mobile and Portable X-ray systems which are used continually in a single location for a period of greater than one week shall be considered a stationary radiographic system and shall meet the requirements of RHB 4.4, as discussed in RHB 4.8.8.

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEW (See RHB 4.4 and Appendix B)

The following information must be provided to the Department for review and approval of a shielding plan:

1. Plans shall show, as a minimum, the following:

    a) The general direction of the useful beam, location of any windows and doors, the location of the operator's booth, the location of the x-ray control panel, and the location of the wall bucky or chest board, if applicable.

    b) The structural composition and thickness or lead equivalency of all walls, doors, partitions, floor, and ceiling of the room concerned.

    c) The dimensions of the room concerned.

    d) The type of occupancy of all adjacent areas inclusive of space above and below the room concerned. If there is an exterior wall, the distance to the closest area where it is likely that individuals may be present must be given.

    e) The make and model of the x-ray equipment and the maximum technique factors.

    f) The type of examinations or treatments which will be performed with the equipment.

    g) Location of the darkroom and the area where the film will be stored. Any shielding which will be used to protect the film must be noted. Include the type of film bin and the type and thickness of the material from which it is constructed. If no film bin will be used, this must also be noted.

2. Information on the anticipated workload of the x-ray system. Give the number of exposures per week. This is the total number of exposures, not patients, taken each week. This figure should include allowances for future growth so that shielding will continue to remain adequate.

3. The most common exam and the average technique factors for this exam must be included. The mA, kVp, exposure time, and number of exposures per week will allow the workload of the facility to be calculated. If exposures are phototimed, include manual backup techniques.

4. Include all source-to-image distances (SIDs) used and the percent of time each will be used. Include the percent of time the beam will be directed toward the table and the chest board, upright bucky, or head unit, if applicable.

A Check or Money Order payable to SCDHEC in the amount of $62.50 must be submitted.

DESIGN REQUIREMENTS FOR AN OPERATOR'S BOOTH (See RHB 4.4.10)

1. SPACE REQUIREMENTS

a) The operator must have 7.5 square feet (0.697 m^2) of unobstructed floor space in the booth.

b) The operator's booth may be any geometric configuration with no dimension less than 2 feet (0.61 m).

c) The space shall be allotted excluding any encumbrance by the x-ray control panel, such as overhang, cables, or other similar encroachments.

d) The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette cannot reach the operator's station in the booth.

2. STRUCTURAL REQUIREMENTS

a) The booth walls shall be permanently fixed barriers of at least 7 feet (2.13 m) high.

b) When a door or moveable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed.

c) If raw building materials do not provide adequate shielding, then an area survey must be performed.

3. X-RAY CONTROL PLACEMENT

a) The x-ray control shall be fixed within the booth and shall be at least 40 inches (1.02 m) from any open edge of the booth wall which is nearest to the examination table.

b) The x-ray control shall allow the operator to use the majority of the available viewing windows.

4. VIEWING SYSTEM REQUIREMENTS

a) Each booth shall have at least one viewing device which will be placed so that the operator can view the patient during each exposure, and allow the operator to have full view of any occupant of the room. The device should also be placed so that the operator can view any entry into the room. If any door which allows access to the room cannot be seen from the booth, then that door must have an interlock controlling the exposure which will prevent the exposure if the door is not closed.

b) When the viewing system is a window, it must have at least 1 square foot (0.0929 m^2) of viewing area. The design of the booth shall be such that the operator's position when viewing the patient and operating the x-ray system is at least 18 inches (0.457 m) from the edge of the booth. The view window must have the same lead equivalence as that required in the booth's wall in which it is mounted.

c) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the same general requirements as discussed in (a) above.

d) When the viewing system is by electronic means, the camera shall be so located as to accomplish the general requirements of (a) above, and there shall be an alternate viewing system as a backup for the primary system.

POST INSTALLATION REQUIREMENTS (See RHB 4.4.4 and RHB 4.4.7 (if applicable))

After construction and installation are complete, the facility must submit "as-built" drawings to the Department for review. The drawings shall indicate the composition of all walls, floors, ceilings, windows, and doors and the placement of the x-ray equipment to include the location of the table, control, and vertical cassette holder if provided. "As-built" drawings may be submitted after shielding installation is complete while cosmetic finishing continues. **X-RAY EQUIPMENT SHALL NOT BE USED BEFORE A SHIELDING PLAN FOR THE UNIT IS APPROVED.**

After installation of a radiation machine, the facility must maintain a scale drawing of the room in which a stationary radiation machine is located, with the drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. The drawing must also include either the results of a survey performed by a Class IX vendor or radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions, or the type and thickness of materials, or lead equivalency of each protective barrier. After approval and installation, an area survey **MUST** be performed when ordinary building materials such as brick, concrete, and sheetrock are not sufficient. In addition, under RHB 4.4.7, the Department has the authority to require an area survey when it deems appropriate.

QUESTIONS

If you have questions, please feel free to call or write:

Bureau of Radiological Health
S.C. DHEC
2600 Bull Street
Columbia, SC 29201
(803) 545-4400
Fax # (803) 545-4412

Regulatory Guides

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